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**DATE MAILED:** 05/19/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~30~~ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

**Part II SUMMARY OF ACTION**

1. ☒ Claims 26-41 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-25 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 26-41 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other



EXAMINER'S ACTION

1) Claims 26-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26 and 32 are indefinite because it is unclear if the outer layer becomes biaxially oriented during the coextrusion step or during the drawing step. It is suggested to amend claims 26 and 32 by reciting that the drawing and radially expanding step (in contrast to the coextrusion step) biaxially orients the outer layer. Claims 26 and 32 are indefinite because it is unclear if the recitation of "forming therewith a layer combination" is a step in addition to the step of coextruding. Claims 26 and 32 are indefinite because it is unclear if the coaxially layered tubular parison is formed by the step of coextruding" or "the method selected from melt bonding and glue adhesion or a combination thereof". It is suggested to insert --forming a coaxially layered tubular parison-- before "co-extruding" on line 4 of claims 26 and 32, delete ", forming therewith a layer combination" on line 9 of claims 26 and 32 and to delete --to form coaxially layered tubular parison-- on lines 12 and 13 of claims 26 and 32. Claims 26 and 32 are indefinite because the scope and meaning of phrase "the inner bonding layer further being one which adheres readily to a catheter body using a method selected from melt bonding and glue adhesion or a

combination thereof" is unclear. For example, does the above phrase limit the material of the bonding layer to a material which melts? Should "same" in claims 26 and 32 be --parison--? Claims 26 and 32 are indefinite because it is unclear which step or steps formed the expander.

Claims 36 and 37 are indefinite because the difference in scope between claims 36 and 37 is unclear. Claims 30, 31 and 38-40 are indefinite because the scope of the recitation of "various ionomers" and "polyethylene type I-IV" is unclear. Furthermore, the members of the markush group are not mutually exclusive. For example: it is noted that the recitation of polyolefins is generic to polyethylene. Claim 40 is indefinite because it is unclear how it further limits claim 39.

2) Claim 40 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The limitation of claim 40 appears to be already recited in claim 39.

3) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to adequately teach how to make/use the invention, i.e. failing to provide an enabling disclosure.

Step (a) of claims 26 and 32 require the coextrusion step to form an outer layer which "consists essentially of a biaxially oriented polymeric film" (emphasis added). The specification fails to adequately explain or teach how to biaxially orient the outer tensile layer during the coextrusion step.

4) Claims 26-41 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

It is suggested to amend claims 26 and 32 by reciting that the drawing and radially expanding step (in contrast to the coextrusion step) biaxially orients the outer layer.

5) The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102

> of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

6) Claims 26-31 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy.

Wang et al[1], directed to the catheter art, discloses coextruding a tube wherein the coextruded tube has an outer layer and an inner layer and forming the tube into a balloon such that the outer layer is biaxially oriented and the inner layer can be heat bonded to a catheter. The outer layer may be made from polyethylene terephthalate and the inner layer may be made from polyethylene. At columns 5 and 6, Wang et al discloses heating the tube, drawing it and expanding it, but does not specifically disclose heating and drawing the balloon so that it exhibits a burst strength greater than seven atmospheres.

Levy, also directed to the catheter art, teaches heating a polyethylene terephthalate tube, drawing the tube and radially expanding the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm).

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[1]Wang et al (US Patent 5,195,969) is prior art under 35 USC 102 since (a) US Patent 5,195,969 was filed before the filing date of this application and (b) none of the claims in this application are entitled to benefit of the filing date of the parent application. It is noted that this application is a CIP of the parent application and that none of the claims in this application are fully supported by the disclosure of the parent application.

As to claim 26, it would have been obvious to heat the coextruded tube of Wang et al, draw the coextruded tube and radially expand the coextruded tube so the outer layer is biaxially oriented and the balloon has a burst pressure of at least 200 psi (13.6 atm) since (a) Wang et al and Levy both disclose forming a balloon for a catheter from a tube and (b) Levy suggests that a biaxially oriented balloon, which was made by heating a tube, drawing the tube and radially expanding the tube and which has a burst pressure of at least 200 psi (13.6 atm), is especially useful in medical dilation procedures.

The limitation of claims 27 and 28 would have been obvious in view of Wang et al's teaching to melt the inner layer of the balloon to heat bond the balloon to a catheter tube. The limitation of claim 30 would have been obvious in view of Wang et al's teaching that the material of the outer layer may be polyethylene terephthalate. The limitation of claim 29 would have been obvious in view of Wang et al's teaching to make the outer layer out of polyesters or polyamides and to melt the inner layer instead of the outer layer during heat bonding of the balloon to a catheter. The limitation of the bonding material as set forth in claims 30 and 31 would have been obvious in view of Wang et al's teaching to make the inner layer out of polyethylene.

7) Claims 32-41 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy as applied above and further in view of Merrill and Lambert.

Wang et al does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claim 32, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic since (a) Wang et al teaches bonding the balloon which comprises the outer layer to a catheter tube to form a catheter and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

The limitation of claim 35 would have been obvious in view of Merrill teaching to use N-vinyl pyrrolidone as a hydrophilic material. The limitations of claims 33, 34 and 36-40 would have been obvious for the reasons given above with respect to claims 27-31. The limitation of claim 41 would have been obvious in

view of Wang et al's teaching to melt the inner layer of the balloon to heat bond the balloon to a catheter tube and to melt the inner layer instead of the outer layer during heat bonding of the balloon to a catheter.

8) Claims 26-31 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Dyke, "Coextruded composite film" by Parker and either JA 53-45353 or Wiggins et al.

Levy, directed to a balloon for a catheter, discloses extruding a tube of polyethylene terephthalate, heating the tube and drawing the tube and inflating the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm). At col 4 lines 45-50, Levy discloses fabricating the balloon catheter comprising the balloon by means of conventional techniques.

Dyke, directed to a balloon catheter, teaches forming a balloon with integral thermoplastic bands and sealing the balloon to a catheter tube by fusing the thermoplastic bands with heat.

Parker, directed to coextruded composite film, teaches bringing a first layer and second layer of polymers into contact in a single die while they are still in a molten state, extruding the layers from the die to form a tube and inflating the tube with air to stretch the tube to a desired thickness. Parker teaches bonding takes place inside the extruder die head and the film leaves the die as a completely multilayered structure.

Parker et al teaches that by providing the second layer a "good heating film" having the all the desired properties of the first layer can be obtained. Parker specifically discloses: "All coextruded films offer freedom from pinholes; it is virtually impossible for a pinhole in one film layer to line up with a pinhole which exits in another film." Parker lists "[a]dhesion to other substrates with or without adhesives" as being one of the "property advantages offered by specially tailored coextruded composite films"

JA 53-45353, directed to a stretched double layer film teaches melting two different resins, extruding them to form a laminated tube and then inflating the tube to stretch it to form a biaxially oriented double layer tube having good heat sealablity.

Wiggins et al, directed to forming a tube having an oriented layer and a heat sealable layer, teaches heat sealing an oreinted film results in heat seals which are weak and not smooth since orientation is adversely affected by heat. Wiggins et al teaches coextruding two types of plastic to form a tube and then inflating the tube to form a tube which has an oriented layer and is heat sealable at lower temperatures.

As to claim 26, it would have been obvious to coextrude the plastic material described by Levy with heat sealable plastic material to form a double layer tube before the steps of heating

the tube, drawing the tube and radially expanding the tube to form the balloon since (a) Levy teaches fabricating a catheter comprising the balloon using a conventional technique, (b) Dyke suggests providing a double layer balloon having an outer layer and an inner heat sealable layer (two bands) so that a catheter comprising the balloon can be fabricated by sealing the balloon to a catheter tube with heat, (c) Parker suggests coextruding a low melting point plastic material with a high melting point plastic material in order to form a double layer tube which has good sealing properties and is virtually free from pinholes and (d) either (i) JA 53-45353 teaches extruding two different plastic materials to form a double layer tube and inflating the tube to form a biaxially oriented tube having "good heat sealablity and flexibility" or (ii) Wiggins et al teaches extruding different plastic materials to form a tube and inflating the tube to form an oriented tube which may be sealed at a lower temperature.

The limitation of claims 27 and 28 would have been obvious in view of Dyke's teaching to heat the inner layer (heat sealable bans) of the balloon to fuse the balloon to a catheter tube. The limitation of claim 30 would have been obvious in view of Levy's al's teaching that the biaxially oriented material of the balloon may be polyethylene terephthalate. The limitation of claim 29 would have been obvious in view of (a) Levy's teaching to make

the biaxially oriented material out of polyethylene terephthalate (a polyester) and (b) Parker and either JA 53-45353 or Wiggins et al's teaching to make one of the layers of a tube out of a material which has a lower melting point than the material of another layer. The limitation of the bonding material as set forth in claims 30 and 31 would have been obvious in view Parker's teaching to make a sealable layer out of polyethylene, JA 53-45353's teaching to make the heat sealable layer out of polyethylene or Wiggins et al's teaching to make the heat sealable layer out of ethylene vinyl acetate.

9) Claims 32-41 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Dyke, Parker and either JA 53-45353 or Wiggins et al as applied above and further in view of Merrill and Lambert.

Levy does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claim 32, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic since (a) Levy teaches fabricating a catheter comprising the balloon and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

The limitation of claim 35 would have been obvious in view of Merrill's teaching to use N-vinyl pyrrolidone as a hydrophilic material. The limitations of claims 33, 34 and 36-40 would have been obvious for the reasons given above with respect to claims 27-31. The limitation of claim 41 would have been obvious in view of Dyke's teaching to heat the inner layer (heat sealable bans) of the balloon to fuse the balloon to a catheter tube and Parker and either JA 53-45353 or Wiggins et al's teaching to make one layer of a tube out of a material which has a lower melting point than the material of another layer.

10) REMARKS

JA 53-45353 refers to application 44-86876 on page 242 for the construction of the composite die 1. JA 51-28668 (which matured from 44-86876) is cited of interest to show a die for coextrusion.

11) No claim is allowed.

12) Any inquiry concerning this communication should be directed to Steven D. Maki at telephone number (703) 308-2068.

Steven D. Maki
May 12, 1994

5-12-94

STEVEN D. MAKI
PATENT EXAMINER
GROUP 1300